K002366

SEP 1 8 2000

SUMMARY OF SAFETY AND EFFECTIVENESS

QUEST MYOCARDIAL PROTECTION SYSTEM BACK-UP SET

I. General Information

A. Generic Name:	Cardioplegia Delivery System
B. Trade Name of Device:	MPS® Back – UP System
C. Applicant's Name and Address:	Quest Medical, Inc. One Allentown Pkwy Allen, TX 75002
D. Premarket Notification Number:	Not assigned to date

II. Indication for Use

The Quest MPS® Back-up System, when used in conjunction with the MPS Console and the Cardioplegia Delivery Set, is indicated for delivery of cardioplegic solutions to the heart during open-heart surgery.

III. Device Description

The MPS Back-up System is designed to replace the MPS Console in the event of shutdown. The MPS Back-up System pumping subsystem facilitates the delivery of the desired concentration of blood, additive and arrest agents to the heart. The subsystem consist of a mechanical pumping device acting on a disposable cassette to deliver fluid. Two manually driven pump pistons displace the contents of the constrained cassette. A pressure monitoring device located on the device housing help ensure the proper fluid delivery pressure. The pump consist of two manually driven pistons and a symmetrically designed pump cassette with two chambers. Each chamber is designed to alternately fill and pump blood. As one chamber fills, the second is delivering fluid. This overlapping and alternating operation of the pumping system provides constant fluid output. The fluid delivery rate is directly related to the speed and frequency of crank revolution. An increase in RPM equals greater delivery.
A pressure-monitoring device located on the device housing ensures proper fluid delivery pressure.

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IV. Device Classification: Class II

Quest Myocardial Protection System Back-up System are reviewed by the FDA Cardiovascular (CV) and (HO) General Hospital Classification Panels. The Product Classification Codes and Panel Codes for this device and predicate devices are:

80 DWK Pump, Infusion, Cardiovascular	21 CFR 880.5725
74 DTR Cardiovascular bypass, Heat exchanger	21 CFR 870.4240
74 DRS Transducer, Blood-Pressure, Extravascular	21 CFR 870.285
74 DXS Cardiopulmonary bypass coronary pressure gauge	21 CFR 870.4310
74 DWF Cardiopulmonary bypass vascular catheter, cannula, or tubing	21 CFR 870.4210
74 KRL Cardiopulmonary bypass bubble detector	21 CFR 870.4205

V. Safety and Effectiveness

Substantial Equivalence:
This device has been shown to be substantially equivalent to the Quest Myocardial Protection System (#K953838).

VI. Other Safety and Effectiveness Data

Sterilization:	Validated SAL of 10^{-6}
Pyrogenicity:	Non-Pyrogenic per USP Pyrogen Test (LAL)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2000

Mr. Doug Bryan
Plant QA/RA Manager
Quest Medical, Inc.
One Allentown Parkway
Allen, TX 75002-4211

Re: K002366
Myocardial Protection System Back-up System
Regulatory Class: II
Product Codes: DWK, DTR, DXS, KRL, DRS, DWF
Dated: July 26, 2000
Received: July 27, 2000

Dear Mr. Bryan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), or if you have questions on the promotion and advertising of your device, please contact the Office of Compliance at (301)594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE FORM

510(K) #:

Device Name: **Quest Myocardial Protection System Back-up Set**

Indications for Use:

The Quest Myocardial Protection System Back-up System, when used in conjunction with the MPS Console and the Cardioplegia Delivery System is intended for use by perfusionist and surgeons trained in delivering cardioplegia solutions to the myocardium during open-heart surgery.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **or** **Over-The –Counter Use**____

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K002366